

Media Release

mylife Loop improves health of pregnant women with type 1 diabetes and their babies

Burgdorf, 12.10.2023, 7 a.m. – Pregnant women with type 1 diabetes and their babies benefit from treatment with a hybrid closed loop system based on the CamAPS FX algorithm. This is demonstrated by the AiDAPT clinical study, which clinical outcomes were published in the New England Journal of Medicine and the experience of the pregnant women in Diabetes Technology and Therapeutics, both on 5 October 2023.^{1,2} The algorithm of Ypsomed's mylife Loop, the CamAPS FX app is the only automated insulin delivery (AID) algorithm approved for pregnant women with type 1 diabetes.

Women with type 1 diabetes have difficulties achieving the tight glycaemic targets required due to their hormonal shifts and changed eating habits during pregnancy. Managing type 1 diabetes currently can result in hypoglycemia, weight gain and high blood pressure in the mother. It is accompanied by increased risk of premature birth, need for intensive care after birth, as well as high birth weight, increasing the lifelong risk of overweight and obesity in children. One in two newborns is affected by common complications related to type 1 diabetes.

“We know that for women with type 1 diabetes, unborn babies are exquisitely sensitive to small rises in blood sugars, so keeping blood sugar levels within the normal range during pregnancy is crucial to reduce risks for the mother and child”, says Dr Helen Murphy, leader of the study and professor at the University of East Anglia.

Reducing health risks for mother and child

In this landmark study, women used the CamAPS FX Hybrid Closed Loop technology for more than 95 per cent of the time. Compared to traditional insulin therapy methods, women who used the technology spent more time in the target range for pregnancy glucose levels (3.5 – 7.8 mmol/l) – 68 per cent vs 56 per cent, which is equivalent to an additional two-and-a-half to three hours every day throughout pregnancy, with no increased risk of hypoglycemia. “Previous studies have confirmed that each additional hour spent in the glucose target range reduces the risk of complications”, explains Helen Murphy.

The research team also found that women who used the technology gained 3.5 kg less weight and were less likely to have blood pressure complications during pregnancy. They had fewer additional appointments at the maternity hospital and made fewer out-of-hours calls to maternity units, suggesting that using the Hybrid Closed Loop system could also save time for pregnant women and maternity units.

Improving pregnancy experience for mothers-to-be

The experience of the women using the hybrid closed-loop systems in the AiDAPT study was reported in a separated publication released on the same day, stating that hybrid closed loop lessened the physical, mental

¹ Lee T.M. et al: Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes: a multicentre randomized controlled trial. The New England Journal of Medicine. Oct 5, 2023. DOI: 10.1056/NEJMoa2303911.

² Lawton J. et al: Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy. Diabetes Technol Ther. 2023 Oct 5. DOI: 10.1089/dia.2023.0323.

and emotional demand of diabetes management from women. They described that using such technology increased their confidence to reach glucose target, improved sleep and decreased their stress and anxiety. Overall using a Hybrid Closed Loop had a positive impact on their pregnancy allowing them to live a “more normal life” as stated by one of the participants and improve their relationship with their healthcare team.

“This is the news that pregnant women with type 1 diabetes have been waiting for. It is great to see advances in diabetes technology deliver such improvements for mothers and infants. We are excited to make this groundbreaking technology widely available both for pregnant women, and for those planning pregnancy”, adds Helen Murphy.

About the studies

The AiDAPT (**A**utomated **I**nsulin **D**elivery **A**mongst **P**regnant women with **T**ype 1 diabetes) study involved 124 pregnant women with type 1 diabetes, aged 18 to 45 years, who were treating their condition with daily insulin therapy. Half of them were randomly assigned to Hybrid Closed Loop technology, the other half to traditional insulin therapy with insulin pumps or multiple daily injections. The study took place in nine hospitals in England, Scotland and Northern Ireland and was supported by two clinical trials units (Norwich Clinical Trials Unit & Jaeb Center for health Research). The women took part in the study from the tenth to the twelfth week until the end of pregnancy.

From AiDAPT, 23 participants were interviewed to explore their experience with Hybrid Closed Loop during type 1 pregnancy. The results of those interviews are available in the “Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy” study.

The so-called Hybrid Closed Loop consists of an algorithm installed on a smartphone that communicates with continuous glucose monitoring systems and insulin pumps. The system adjusts the insulin dose to the glucose level every 10 to 12 minutes, i.e. it continuously reacts to the persistent changes in the glucose level during pregnancy. The study compared this technology to continuous glucose monitoring and insulin delivery systems, which require women to make multiple insulin dosing decisions each day.

The researchers note that the study was too small to examine in detail the health consequences for the baby, and the results are specific to the CamAPS FX technology.

About Ypsomed

Ypsomed is the leading developer and manufacturer of injection and infusion systems for self-medication and a renowned diabetes specialist with over 35 years of experience. As a leader in innovation and technology, it is a preferred partner of pharmaceutical and biotech companies for pens, autoinjectors and pump systems for administering liquid medications. Ypsomed presents and markets its product portfolios under the umbrella brands mylife Diabetescare directly to patients or via pharmacies and hospitals as well as under YDS Ypsomed Delivery Systems in business-to-business operations with pharmaceutical companies. The company is headquartered in Burgdorf, Switzerland, and has a global network of production facilities, subsidiaries and distribution partners employing a staff of over 2,200 employees worldwide.

Contact

Susanne Koehler, Public Relations, Ypsomed Holding AG
+41 34 424 47 32, susanne.koehler@ypsomed.com

Ypsomed Holding AG

Brunnmattstrasse 6
3401 Burgdorf / Switzerland
www.ypsomed.com